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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,030	03/17/2004	Patrick Benoit	08888.0530-01	3970

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,030	BENOIT ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Preliminary Amendment filed December 23, 2005.

Claims 1-21 are pending in the instant application.

Claims 1-21 are subject to a restriction requirement as detailed below:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1, 2, 7, and 9-19, drawn to a polynucleotide comprising a fragment of SEQ ID NO:3, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:3, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide and an expression cassette comprising said polynucleotide, classifiable in class 536, subclass 24.5.

Group II. Claims 1, 2, 7, and 9-19, drawn to a polynucleotide comprising a fragment of SEQ ID NO:4, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:4, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said

polynucleotide and an expression cassette comprising said polynucleotide, classifiable in class 536, subclass 24.5.

Group III. Claims 1, 2, 7, and 9-19, drawn to a polynucleotide comprising a fragment of SEQ ID NO:5, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:5, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide and a vector comprising said polynucleotide, classifiable in class 536, subclass 24.5.

Group IV. Claims 1, 2, 7, and 9-19, drawn to a polynucleotide comprising a fragment of SEQ ID NO:6, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:6, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide and an expression cassette comprising said polynucleotide, classifiable in class 536, subclass 24.5.

Group V. Claims 1, 2, 7, and 9-19, drawn to a polynucleotide comprising a fragment of SEQ ID NO:7, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:7, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said

polynucleotide and an expression cassette comprising said polynucleotide, classifiable in class 536, subclass 24.5.

Group VI. Claims 1, 7, and 8, drawn to an expression cassette comprising a polynucleotide comprising a fragment of SEQ ID NO:3, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:3, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide and further comprising SEQ ID NO:9, classifiable in class 536, subclass 24.5.

Group VII. Claims 1, 7, and 8, drawn to an expression cassette comprising a polynucleotide comprising a fragment of SEQ ID NO:4, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:4, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide and further comprising SEQ ID NO:9, classifiable in class 536, subclass 24.5.

Group VIII. Claims 1, 7, and 8, drawn to an expression cassette comprising a polynucleotide comprising a fragment of SEQ ID NO:5, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:5, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a

gene which is operably linked to said polynucleotide and further comprising SEQ ID NO:9, classifiable in class 536, subclass 24.5.

Group IX. Claims 1, 7, and 8, drawn to an expression cassette comprising a polynucleotide comprising a fragment of SEQ ID NO:6, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:6, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide and further comprising SEQ ID NO:9, classifiable in class 536, subclass 24.5.

Group X. Claims 1, 7, and 8, drawn to an expression cassette comprising a polynucleotide comprising a fragment of SEQ ID NO:7, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:7, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide and further comprising SEQ ID NO:9, classifiable in class 536, subclass 24.5.

Group XI. Claim 20, drawn to a method for expressing a protein or an RNA of therapeutic interest in cardiac cells *in vivo*, comprising preparing and introducing into cells an expression cassette comprising a polynucleotide comprising a fragment of SEQ ID NO:3, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:3, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce

expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide, classifiable in class 435, subclass 91.1.

Group XII. Claim 20, drawn to a method for expressing a protein or an RNA of therapeutic interest in cardiac cells *in vivo*, comprising preparing and introducing into cells an expression cassette comprising a polynucleotide comprising a fragment of SEQ ID NO:4, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:4, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide, classifiable in class 435, subclass 91.1.

Group XIII. Claim 20, drawn to a method for expressing a protein or an RNA of therapeutic interest in cardiac cells *in vivo*, comprising preparing and introducing into cells an expression cassette comprising a polynucleotide comprising a fragment of SEQ ID NO:5, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:5, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide, classifiable in class 435, subclass 91.1.

Group XIV. Claim 20, drawn to a method for expressing a protein or an RNA of therapeutic interest in cardiac cells *in vivo*, comprising preparing and introducing into cells an expression cassette comprising a polynucleotide comprising a fragment of SEQ ID NO:6, or a fragment of a sequence that hybridizes under

high stringency conditions to SEQ ID NO:6, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide, classifiable in class 435, subclass 91.1.

Group XV. Claim 20, drawn to a method for expressing a protein or an RNA of therapeutic interest in cardiac cells *in vivo*, comprising preparing and introducing into cells an expression cassette comprising a polynucleotide comprising a fragment of SEQ ID NO:7, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:7, wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide, classifiable in class 435, subclass 91.1.

Group XVI. Claim 21, drawn to a polynucleotide comprising a fragment of SEQ ID NO:2 or a fragment having at least 80% sequence identity to a fragment of SEQ ID NO:2, wherein said fragment is at least 77 nucleotides in length and wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide, classifiable in class 536, subclass 24.1.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable**

product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Searching the inventions of Groups I-V together would impose a serious search burden. Although the polynucleotides of Groups I-V are related because in the absence of inverted terminal repeat sequences from AV, the polynucleotides specifically induce expression in cardiac cells *in vivo* of a gene which is linked to said polynucleotide, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: They employ different molecules with different chemical and physical structures so that

independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the polynucleotide comprising a fragment of SEQ ID NO:3, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:3 of Group I would not encompass all of the art relevant to the polynucleotides comprising a fragment of SEQ ID NOs:4-7, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NOs:4-7 of Groups II-V, respectively. Similarly, a search of the polynucleotide comprising a fragment of SEQ ID NO:4, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:4 of Group II would not encompass all of the art relevant to the polynucleotides comprising a fragment of SEQ ID NOs:5-7, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NOs:5-7 of Groups II-V, respectively. Similarly, a search of the polynucleotide comprising a fragment of SEQ ID NO:5, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:5 of Group III would not encompass all of the art relevant to the polynucleotides comprising a fragment of SEQ ID NOs:6 and 7, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:6 and 7 of Groups IV and V, respectively. Also a search of the polynucleotide comprising a fragment of SEQ ID NO:6, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:6 of Group IV would not encompass all of the art relevant to the polynucleotide comprising a fragment of SEQ ID NO:7, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NO:7 of Group V. Thus, they are patentably distinct from each other.

Searching the inventions of Groups I-V together with the inventions of Groups VI-X would impose a serious search burden. Although the polynucleotides of Groups I-V are related to the polynucleotides of Groups VI-X because in the absence of inverted terminal repeat sequences from AV, the polynucleotides specifically induce expression in cardiac cells *in vivo* of a gene which is linked to said polynucleotide, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: They employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the polynucleotides comprising a fragment of SEQ ID NOs:3-7, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NOs:3-7 of Groups I-V would not encompass all of the art relevant to the polynucleotides comprising a fragment of SEQ ID NOs:3-7, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NOs:3-7, wherein said polynucleotides further comprise SEQ ID NO:9 of Groups VI-X. Thus, they are patentably distinct from each other. Further, the inventions are distinct because the invention of Groups VI-X recite the addition of SEQ ID NO:9, which is not found or required in Groups I-V. Search and examination of Groups I-V together with the inventions of Groups VI-X in one patent application would result in an undue burden, since the searches for the polynucleotides are not co-extensive. Thus, they are

patentably distinct from each other.

The invention of Groups I-V are related to the method inventions of Groups XI-XV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used in materially different processes of use. For example, the polynucleotides comprising a fragment of SEQ ID NOs:3-7, or a fragment of a sequence that hybridizes under high stringency conditions to SEQ ID NOs:3-7 of Groups I-V can be used in a hybridization probes to identify gene expression, which is a materially different process than a method for expressing a protein or an RNA of therapeutic interest in cardiac cells *in vivo*, as in Groups XI-XV.

The invention of Group XVI constitutes a patentably distinct invention from all other Groups because the invention of Group XVI is drawn to drawn to a polynucleotide comprising a fragment of SEQ ID NO:2 or a fragment having at least 80% sequence identity to a fragment of SEQ ID NO:2, wherein said fragment is at least 77 nucleotides in length and wherein said polynucleotide, in the absence of inverted terminal repeat sequences from AAV specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide which is a polynucleotide not found in any other Group.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be

traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tcg
July 17, 2006